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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,888

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

12/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,888	Applicant(s) DADOURIAN, DANIEL G.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's after final amendment filed 12 November 2008.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn and replaced with the non-final rejection below.

Response to Arguments

Applicant's arguments filed 12 November 2008 have been fully considered but they are not persuasive.

Applicant argues that Ischinger's ostial locator wire does not partially encircle an interventional device. This argument is not persuasive because Applicant is claiming that the locator must partially encircle, not fully encircle the interventional device. Since the ostial locator wire of Ischinger is located over the outside of the interventional device, it reads on the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ischinger (US Patent 6,682,556).

Claim 1: Ischinger'556 discloses a device with a sheath (14) adapted to be affixed to an interventional device (40 and balloon; see Figure 2a) and an ostial locator wire (15, 100) having a distal region capable of moving between an extended and retracted configuration (column 4, lines 23-34). The sheath is affixed to the interventional device (see Figure 2a).

Claim 23, 24: Ischinger'556 discloses a device that contains an interventional device (40 and balloon; see Figure 2a), a sheath (14) and an ostial locator (15, 100) disposed within the sheath that is capable of moving between an extended and retracted configuration (column 4, lines 23-34). Further, Ischinger'556 discloses that when deploying a stent at an ostium, multiple wires (15, 100) can be used to create an ostial locator that surrounds the stent (column 4, lines 29-32).

Claims 1, 7, 9-11, 15, 23-25, 27, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Saltiel (US Patent 6,458,151).

Claim 1, 7, 9: Saltiel'151 teaches a sheath (32) and an ostial locator wire (22) slidably disposed within the sheath (column 4, lines 4-5). The locator (22) has a retracted configuration within the sheath and an expanded configuration when extended (column 4, lines 4-21). The ostial locator can contain a wire because it is made out of a mesh formed of nickel-titanium alloy (column 3, lines 45-51).

Claim 10: The ostial locator wire has an atraumatic tip (column 3, lines 55-57).

Claim 11: The distal end is a lasso.

Claim 15: Saltiel'151 teaches that it is known to make the distal region of the ostial locator radiopaque (column 6, lines 23-26).

Claim 23: Saltiel'151 teaches an interventional device (100), a sheath (32) and an ostial locator (20) slidably disposed within the sheath (column 4, lines 4-5) and encircles but is spaced apart from the stent in the expanded configuration.

Claim 24: The interventional device contains a balloon surrounded by a stent (Figure 4a).

Claim 25: The ostial locator can contain a wire because it is made out of a mesh formed of nickel-titanium alloy (column 3, lines 45-51).

Claim 27: The interventional device contains a delivery catheter for delivering the stent into the ostium (50).

Claim 28: The delivery catheter (50) is affixed to the sheath (32) so that the distal end of the sheath (32) is proximal to the stent in the delivery configuration (during delivery).

Claims 23, 26, 29, 33, 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. (US Patent 2004/0111143).

Claim 23, 26, 29, 33, 34: Fischell teaches a sheath (40), and an ostial locator (23) that is extendable from the lumen of the sheath (Figures 3, 4). The locator is capable of partially encircling an interventional device (18). The locator further is flattened out axially when it is located outside an ostium (see Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel'151, as applied to Claim 1, in further view of McGuckin, et al. (US Patent 6,589,214).

Saltiel'151 teaches that the sheath is attached to the interventional device, but does not disclose what is used to attach the interventional device and sheath.

Saltiel'151 does not teach a specific method of attaching the sheath to the interventional device, however, it is old and well known in the art to attach using clasps and sheaths. Further, the multiple attachment methods claimed are obvious variants of one another.

McGuckin'214 teaches an introducer sheath containing a fastener (40) that can be used to attach an interventional device to a sheath (21). Regarding Claim 3, the fastener (40) comprises a thin flexible sheet that can wrap around an interventional

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device. Regarding Claim 4 and 5, the fastener contains a clasp (85) (column 6, lines 21-28), which is friction fit into engagement with the fastener (40) so the fastener can retain an interventional device (column 6, lines 21-28). Regarding Claim 6, the clasp (85) is adapted to be fit to an interventional device using a biocompatible adhesive. It would have been obvious to one skilled in the art at the time the invention was made to modify Saltiel'151 with a different attachment mechanism, such as the one taught by McGuckin'214 to make sure that the sheath and an interventional device are securely fastened to each other and not lost in the patient's body.

Claims 1, 8, 12-14, 29, 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell'143 in view of Stewart et al. (US Patent 6,572,612).

Claim 1, 8, 12, 13, 14, 29, 30, 31: Fischell teaches a sheath (40), and an ostial locator (23) that is extendable from the lumen of the sheath (Figures 3, 4). The locator is capable of partially encircling an interventional device (18). The locator further is flattened out axially when it is located outside an ostium (see Figure 6). Fischell doesn't teach that the ostial locator is a wire that assumes a three dimensional shape before being flattened out.

Stewart'612 teaches an ostial locator device (Figure 3a-3d). The ostial locator has a spiral shape and flattens out when placed in contact with an ostium (Figure 3d). Stewart'612 further teaches that the device can assume an expanded configuration when advanced outside of a sheath in a different embodiment (Figure 10; column 15, lines 40-46). It would be obvious to modify the ostial locator configuration taught by

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Fischell'143 with the ostial locator taught by Stewart'612 because Stewart's locator can be used to identify when the locator is in contact with the ostium (column 9, lines 29-39).

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell'143, as applied to claim 29 above, and further in view of Ravenscroft (US Patent 5,702,418).

Fischell'143 teach the limitations of Claim 32 except for a stop that limits the distal end from being over extended.

Stops that prevent overextension of devices into the body are old and well known in the art, as for example, the stop (26) taught by Ravenscroft stops the distal end of the element 15 from overextending into the body. It would have been obvious to one of ordinary skill in the art to modify the device taught by Fischell'143 with a stop in order to prevent the distal end from over extending into the body and possibly getting lost or left behind causing harm to the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773